

***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 60807-AA-PCT-US/ JPW/GJG/DJK		Serial No. Not Yet Known 10/792,311							
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Alexander Gad and Dora Lis		Filing Date Herewith		Group Art Unit 1644					
U.S. PATENT DOCUMENTS													
Examiner Initial		Document Number				Date	Name	Class	Subclass	Filing Date if Appropriate			
PJK ↓ ✓		3	8	4	9	5	5	0	11/19/74	Teitelbaum, et al.			
		3	9	9	1	2	1	0	11/09/76	Shea			
		4	3	3	9	4	3	1	7/13/82	Gaffar			
		5	2	0	4	0	9	9	4/20/93	Barbier, et al.			
		5	5	5	4	3	7	2	9/10/96	Hunter et al.			
		5	5	8	3	0	3	1	12/10/96	Stern			
		5	5	9	1	6	2	9	1/7/97	Rodriguez, et al.			
		5	6	2	3	0	5	2	4/22/97	McLean et al.			
✓		5	6	2	7	2	0	6	5/6/97	Hupe, et al.			
		5	6	6	8	1	1	7	9/16/97	Shapiro, et al.			
		5	7	1	9	2	9	6	2/17/98	Acton, et al.			
FOREIGN PATENT DOCUMENTS													
		Document Number				Date	Country	Class	Subclass	Translation Yes No			
PJK ↓ ✓	WO	8	8	0	2	1	3	9	12/29/88	US			
	WO	9	2	0	2	5	4	3	2/20/92	Europe			
	WO	9	4	0	3	4	8	4	2/17/94	US			
	WO	9	4	2	6	7	7	4	11/24/94	US			
	WO	9	5	2	6	9	8	0	10/12/95	US			
	WO	9	5	3	1	9	9	7	11/30/95	US			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)													
PJK ↓ ✓		Abramsky, et al., "Effect of a Synthetic Polypeptide (COP-1) on Patients with Multiple Sclerosis and with Acute Disseminated Encephalomyelitis", <u>J. Neurol. Sci.</u> , 1977, <u>31</u> , 433-438											
		Aharoni, et al., "T Suppressor Hybridomas and Interleukin-2-Dependent Lines Induced by Copolymer 1 or by Spinal Cord Homogenate Down-Regulate Experimental Allergic Encephalomyelitis", <u>Eur. J. Immunol.</u> , 1993, <u>23</u> , 17-25;											
		Aharoni, et al., "Studies on the Mechanism and Specificity of the Effect of the Synthetic Random Copolymer GLAT on Graft-versus-Host Disease", <u>Immunol. Letters</u> , 1997, <u>58</u> , 79-87;											
		Alvord, et al., "Myelin Basic Protein Treatment of Experimental Allergic Encephalomyelitis in Monkeys", <u>Ann. Neurol.</u> , 1979, <u>6</u> , 469-473											
✓		Amon, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Copolymer Immunological Cross Reactive with Basic Encephalitogen", <u>Israel J. Med. Sci.</u> , 1972, <u>8</u> , 1759-1760;											
	EXAMINER		DATE CONSIDERED										
PJK ↓ ✓		12/14/04											
<small>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>													

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 60807-AA-PCT-US/ JPW/GJG/DJK		Serial No. Not Yet Known <u>10/792,311</u>	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Alexander Gad and Dora Lis		Filing Date Herewith	
						Group Art Unit <u>1644</u>	
U.S. PATENT DOCUMENTS							
Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
PJK ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	5 7 3 4 0 2 3	3/31/98	Bishwajit et al.				
	5 8 0 0 8 0 8	9/1/98	Konfino, et al.				
	5 8 5 8 9 6 4	1/12/99	Aharoni, et al.				
	5 8 8 6 1 5 6	3/23/99	McLean et al.				
	5 9 5 8 9 7 2	9/28/99	Hupe, et al.				
	5 9 8 1 5 8 9	11/9/99	Konfino, et al.				
	6 0 4 8 8 9 8	4/11/00	Konfino, et al.				
	6 0 5 4 4 3 0	4/25/00	Konfino, et al.				
	6 2 1 4 7 9 1	4/10/01	Arnon, et al.				
	6 3 4 2 4 7 6	1/29/02	Konfino, et al.				
	6 3 6 2 1 6 1	3/26/02	Konfino, et al.				
FOREIGN PATENT DOCUMENTS							
	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
PJK ↓ ↓ ↓ ↓ ↓	WO 9 5 3 1 9 9 0	11/30/95	US				
	WO 9 5 3 3 4 7 5	12/14/95	Europe				
	WO 9 8 3 0 2 2 7	7/16/98	US				
	WO 0 0 0 5 2 4 9	2/3/00	US				
	WO 0 0 0 5 2 5 0	2/3/00	US				
	WO 0 0 1 8 7 9 4	4/6/00	US				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
PJK ↓ ↓ ↓ ↓	Arnon, et al., "Suppression of EAE in Baboons by a Synthetic Polymer of Amino Acids", <u>Neurol.</u> , 1978, <u>28</u> , 336 (Abstract);						
	Arnon, et al., "Desensitization of Experimental Allergic Encephalomyelitis with Synthetic Peptide Analogues" in <u>The Suppression of Experimental Allergic Encephalomyelitis and Multiple Sclerosis</u> (Academic Press, New York, 1980) 105-107;						
	Arnon, "A Synthetic Copolymer of Amino Acids in a Clinical Trial for MS Therapy" in <u>Progress in Multiple Sclerosis Research</u> (Bauer, Ritter, eds., Springer Verlag New York, 1980) 416-418;						
	Arnon, "Experimental Allergic Encephalomyelitis - Susceptibility and Suppression", <u>Immunological Rev.</u> , 1981, <u>55</u> , 5-30;						
	Arnon, et al., "Suppression of Demyelinating Diseases by Synthetic Copolymers", in <u>A Multidisciplinary Approach to Myelin Disease</u> (G. Serlupi Crescenzi, ed., Plenum Publishing Corp., 1988) 243-250						
EXAMINER <u>Phy. N. J. K.</u>			DATE CONSIDERED <u>12/14/04</u>				
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
60807-AA-PCT-US/
JPW/ GJG/DJKSerial No.
Not Yet Known
10/792,311INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Applicants: Alexander Gad and Dora Lis

Filing Date
HerewithGroup Art Unit
1644

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
PNT	6 5 1 4 9 3 8	2/4/03	Gad et al.			
	6 6 2 0 8 4 7	9/16/03	Konfino, et al.			
	20 01 00 55 56 8 A1	12/27/01	Gilbert, et al.			
	20 02 00 37 84 8 A1	03/28/02	Eisenbach-Schwartz et al.			
	20 02 01 07 38 8 A1	08/08/02	Vandenbark			
	20 02 01 15 10 3 A1	8/22/02	Gad, et al.			
	20 03 00 04 09 9 A1	01/02/03	Eisenbach-Schwartz et al.			
	09 3 5 9 0 9 9	7/22/99	Strominger, et al.			
	09 4 8 7 7 9 3	1/20/00				
	09 6 2 0 2 1 6	7/20/02				
✓	09 7 6 5 3 0 1					

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
PNT	WO 0 0 2 0 0 1 0	4/13/00	US				
	WO 0 0 2 7 4 1 7	5/18/00	US				
	WO 0 1 5 2 8 7 8	7/26/01	US				
	WO 0 1 6 0 3 9 2	8/23/01	US				
	WO 0 1 9 3 8 9 3	12/3/01	US				
✓	WO 0 1 9 3 8 2 8	12/13/01	US				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

PNT	Pending claims of U.S. Serial No. 09/816,989 (Gad et al.)(Item 28)., U.S. Patent Publication No. 20020115103 A1, for the Examiner's convenience
	Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by Cop-1 - Relevance to Multiple Sclerosis", <u>Israel J. Med. Sci.</u> , 1989, <u>25</u> , 686-689;
	Arnon, et al., "Immunomodulation of Experimental Allergic Encephalomyelitis", <u>Israel J. Med. Sci.</u> , 1993, <u>29</u> , 175-181;
	Arnon, et al., "On the Existence of Suppressor Cells", <u>Int. Arch. Allergy Immunol.</u> , 1993, <u>100</u> , 2-7;
✓	Arnon, et al., "Immunospecific Drug Design - Prospects for Treatment of Autoimmune Disease", <u>Therapeutic Immunol.</u> , 1994, <u>1</u> , 65-70;

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

12/14/04

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 60807-AA-PCT-US/ JPW/ GJC/DJK		Serial No. Not Yet Known 10/792,311	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Alexander Gad and Dora Lis			
				Filing Date Herewith		Group Art Unit 1644	
U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
PNH		Ben-Nun, et al., "The Autoimmune Reactivity to Myelin Oligodendrocyte Glycoprotein (MOG) in Multiple Sclerosis is Potentially Pathogenic: Effect of Copolymer 1 on MOG-induced Disease", <u>J. Neurol.</u> , 1996, 243(Suppl. 1), S14-S22					
		Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", <u>Ann. Neurol.</u> , 1980, 8, 117 (Abstract)					
		Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", <u>Trans. Am. Neurol. Assoc.</u> , 1980, 105, 348-350;					
		Bornstein, et al., "Multiple Sclerosis: Trial of a Synthetic Polypeptide", <u>Ann. Neurol.</u> , 1982, 11, 317-319;					
		Brosnan, et al., "The Response of Normal Human Lymphocytes to Copolymer 1", <u>J. Neuropath. Exp. Neurol.</u> , 1983, 42, 356 (Abstract)					
		Bornstein, et al., "Clinical Trials of Copolymer 1 in Multiple Sclerosis", <u>Ann. N.Y. Acad. Sci. (USA)</u> , 1984, 366-372					
		Bornstein, et al., "Clinical Trials of a Synthetic Polypeptide (Copolymer 1) for the Treatment of Multiple Sclerosis" in Gonsett et al., <u>Immunological and Clinical Aspects of Multiple Sclerosis</u> (MTP Press, The Hague, 1984) 144-150					
		Bornstein, et al., "Multiple Sclerosis: Clinical Trials of a Synthetic Polypeptide, Copolymer 1", <u>Neurol.</u> , 1985, 35 (Suppl. 1), 103 (Abstract)					
		Bornstein, "Cop 1 May be Beneficial for Patients with Exacerbating-remitting Form of Multiple Sclerosis", <u>Adv. Ther. (USA)</u> , 1987, 4, 206 (Abstract)					
		Bornstein, et al., "A Pilot Trial of Cop 1 in Exacerbating-remitting Multiple Sclerosis", <u>New Eng. J. Med.</u> , 1987, 317(7), 408-414					
		Bornstein, et al., "Clinical Experience with COP-1 in Multiple Sclerosis", <u>Neurol.</u> , 1988, 38(Suppl. 2), 66-69					
✓		Bornstein, et al., "Pilot Trial of COP-1 in Chronic Progressive Multiple Sclerosis: Preliminary Report", from <u>The International Multiple Sclerosis Conference: An Update on Multiple Sclerosis</u> , Roma (Italy), September 15-17, 1988, in <u>Elsevier Science Publisher</u> , 1989, 225-232					
EXAMINER		DATE CONSIDERED					
J. H. A. 2/6		12/14/84					
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 60807-AA-PCT-US/ JPW/ GJG/DJK		Serial No. Not Yet Known 10/792,311	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Alexander Gad and Dora Lis			
				Filing Date Herewith		Group Art Unit 1644	
U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
Pnk		Bornstein, et al., "Clinical Trials of Cop 1 in Multiple Sclerosis" in <u>Handbook of Multiple Sclerosis</u> (S.D. Cook Marcel Rekker, ed., 1990) 469-480					
		Bornstein, et al., "A Placebo-controlled, Double-blind, Randomized Two-center, Pilot Trial of Cop 1 in Chronic Progressive Multiple Sclerosis", <u>Neurol.</u> , 1991, <u>41</u> , 533-539					
		Bornstein, et al., "Treatment of Multiple Sclerosis with Copolymer 1" in <u>Treatment of Multiple Sclerosis: Trial Design, Results and Future Perspectives</u> (Rudick R.A. & Goodkin D.E., eds., Springer Verlag, London, 1992) 173-198					
		Brosnan, et al., "Copolymer 1: Effect on Normal Human Lymphocytes", <u>Ann. N.Y. Acad. Sci. (USA)</u> , 1984, <u>436</u> , 498-499					
		Brosnan, et al., "Immunogenic Potentials of Copolymer 1 in Normal Human Lymphocytes", <u>Neurol.</u> , 1985, <u>35</u> , 1754-1759					
		Burns, et al., "Human Cellular Immune Response in Vitro to Copolymer 1 and Myelin Basic Protein (MBP)", <u>Neurol.</u> , 1985, <u>35</u> (Suppl. 1), 170 (Abstract)					
		Burns, et al., "Human Cellular Immune Response to Copolymer 1 and Myelin Basic Protein", <u>Neurol.</u> , 1986, <u>36</u> , 92-94					
		Burns, et al., "Failure of Copolymer 1 to Inhibit the Human T-cell Response to Myelin Basic Protein", <u>Neurol.</u> , 1991, <u>41</u> , 1317-1319					
		Carter, et al., "Newer Drug Therapies for Multiple Sclerosis", <u>Drug Therapy</u> , 1990, 31-32, 37-39, 42-43					
		Cazzato et al., "Treatment of Multiple Sclerosis. The Present and the Future. Study Group on Diagnosis and Therapy of Multiple Sclerosis", Database Medline on STN, Instituto do Clinica Neurologica, Universit'a, Trieste, Italy: Medline AN: 2000060325, Recent Progressi in Medicina, October 1999, <u>90</u> (10): 538-544 (Abstract)					
		Clinical Trial Protocol No. 9001, Teva Pharmaceutical Industries, Ltd., first patient enrolled October 23, 1991)					
✓		Clinical Trial Protocol No. 9002, Lemmon Co. and Teva Pharmaceutical Industries, Ltd., first patient enrolled June 17, 1993					
EXAMINER Phy N. Jp		DATE CONSIDERED 12/14/04					
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 60807-AA-PCT-US/ JPW/ GJG/DJK		Serial No. Not Yet Known 10792311	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Alexander Gad and Dora Lis			
				Filing Date Herewith		Group Art Unit 1644	
U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
P.H.		Fridkis-Hareli, et al., "Specific and Promiscuous Binding of Synthetic Copolymer I to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", <u>Israeli Biochem. Soc.</u> , 1994, 21-22 (Abstract)					
		Fridkis-Hareli, et al., "Synthetic Copolymer I Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells" in <u>Neurochem Mtg.</u> , August 14-19, 1994					
		Fridkis-Hareli, et al., "Synthetic Copolymer I Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen- Presenting Cells", <u>J. Neurochem.</u> , 1994, 63(Suppl. I), 561					
		Fridkis-Hareli, et al., "Synthetic Copolymer I and Myelin Basic Protein do not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", <u>Department of Chemical Immunology, The Weizmann Institute of Science, Rehovot, Israel</u> , 1994					
		Fridkis-Hareli, et al., "Synthetic Copolymer I and Myelin Basic Protein Do Not Undergo Processing Prior to the Binding to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells", <u>Israeli Immunol. Soc.</u> , May 3-4, 1994 (Abstract)					
		Fridkis-Hareli, et al., "Synthetic Copolymer I and Myelin Basic Protein Do Not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen-Presenting Cells", <u>Cell. Immunol.</u> , 1995, 163, 229-236					
		Fridkis-Hareli, et al., "Promiscuous Binding of Synthetic Copolymer I to Purified HLA-DR Molecules", <u>J. Immunol.</u> , 1998, 160, 4386-4397					
		Fridkis-Hareli, et al., "Synthetic Amino Acid Copolymers that Bind to HLA-DR Proteins and Inhibit Type II Collagen-Reactive T Cell Clones", <u>Proc. Natl. Acad. Sci.</u> , 1998, 95, 12528-12531					
		Fridkis-Hareli et al., "Binding of random copolymers of three amino acids to class II MHC molecules", <u>Intl. Immunol.</u> , 1999, 11(5): 635-641					
		Fridkis-Hareli et al., "Synthetic Peptides that Inhibit Binding of the Collagen Type II 261-273 Epitope to Rheumatoid Arthritis-Associated HLA-DR1 and DR4 Molecules and Collagen-Specific T-cell Responses", <u>Database HCAPLUS on STN, Department of Clinical Immunology, Aarhus University Hospital, Aarhus, Denmark, HCAPLUS AN: 2000:455053, Human Immunology, 2000, 61(7): 640-650 (Abstract)</u>					
		Grgacic, et al., "Cell-mediated Immune Response to Copolymer I in Multiple Sclerosis Measured by the Macrophage Procoagulant Activity Assay", <u>Int. Immunol.</u> , 1990, 2(8), 713-718					
		Gurevich, "Study of the MHC-competition Between BP and Cop 1 Using Human Cytotoxic T-cell Clones", <u>Israel J. Med. Sci.</u> , 1993 (Abstract)					
EXAMINER		DATE CONSIDERED					
J. N. J.		12/12/04					
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 60807-AA-PCT-US/ JPW/GJG/DJK		Serial No. Not Yet Known 16/792,311	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Alexander Gad and Dora Lis		Filing Date Herewith	
				Group Art Unit 1644			
U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
Pnk		Harrison and Hafler, "Antigen-Specific Therapy for Autoimmune Disease", <u>Current Opin. Immunol.</u> , 2000, 12(6): 704-711					
		Henry, Celia M., "Special Delivery", <u>Chem. and Eng. News</u> , Sept. 18, 2000, 49-54					
		Herzenberg et al., "Lack of immune response gene control for induction of epitope-specific suppression by TGA1 antigen", <u>Nature</u> , 1982, 295: 329-331 (Abstract)					
		Jacobs, et al., "Advances in Specific Therapy for Multiple Sclerosis", <u>Neurol.</u> , 1994, 7, 250-254					
		Johnson, "Clinical Studies in Copolymer 1 Therapy for Exacerbating-relapsing Multiple Sclerosis", in <u>Congress for Advances in the Understanding and Treatment of Multiple Sclerosis</u> , Boston (USA), Oct. 28-29, 1992					
		Johnson, "Experimental Therapy of Relapsing-Remitting Multiple Sclerosis with Copolymer-1", <u>Ann. Neurol.</u> , 1994, 36(Suppl.), 115-117					
		Johnson, Management of Relapsing/Remitting Multiple Sclerosis with Copolymer 1 (Copaxone)", <u>Chemical Abstracts</u> , 1996, 125, 291993b					
		Ju et al., "Idiotypic analysis of antibodies against the terpolymer L-glutamic acid 60-L-alanine30-L-tyrosine10 (GAT). IV. Induction of CGAT idiotype following immunization with various synthetic polymers containing glutamic acid and tyrosine", <u>Eur. J. Immunol.</u> , 1979, 9(7): 553-560 (Abstract)					
		Kay, et al., "The Mechanism of Action of FK 506", <u>Transplantation Proceedings</u> , 1990, 22(1, Suppl. 1), 96-99					
		Keith, et al., "The Effect of COP 1, a Synthetic Polypeptide, on Chronic Relapsing Experimental Allergic Encephalomyelitis in Guinea Pigs" <u>J. Neurol. Sci.</u> , 1979, 42, 267-274					
		Keleman, et al., "Graft-versus-Host Disease in Bone Marrow Transplantation: Experimental, Laboratory, and Clinical Contributions of the Last Few Years", <u>Int. Arch. Allergy Immunol.</u> , 1993, 102, 309-320					
✓		Kepsutlu et al., "Evaluation of Chitosan Used as an Excipient in Tablet Formulations", Database HCAPLUS on STN, Department of Pharmaceutical Technology, Gulhane Military Medical Academy, Ankara, 06018, Turkey, HCAPLUS AN: 1999: 590411, Acta. Pol. Pharm. 1999, 56(3): 27-235 (Abstract)					
EXAMINER		DATE CONSIDERED					
Jy d 7p		12/14/04					
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 60807-AA-PCT-US/ JPW/GJG/DJK		Serial No. Not Yet Known 10/792311	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Alexander Gad and Dora Lis			
				Filing Date Herewith		Group Art Unit 1644	
U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
Ynt		Kott, et al., "COP-1 Increases Suppressor Cells Number in Multiple Sclerosis", <u>Israel Neurological Assoc.</u> , December 19-20, 1994, Herzliya (Israel), 17					
		Kropshofer et al., "Self-Peptides from Four HLA-DR Alleles Share Hydrophobic Anchor Residues Near the NH ₂ -Terminal Including Proline as a Stop Signal for Trimming", <u>J. Immunol.</u> , 1993, 151: 4732-4742					
		Lai et al., "Complementation of Class II A alleles in the immune response to (GluLysTyr) polymers", <u>Exp. Clin. Immunogenet.</u> , 1986, 3(1): 38-48 (Abstract)					
		Lai et al., "Monoclonal T cell responses to two epitopes on a single immunogen controlled by two distinct genes", <u>J. Immunol.</u> , 1986, 136(10): 3799-3804 (Abstract)					
		Lando, et al., "Effect of Cyclophosphamide on Suppressor Cell Activity in Mice Unresponsive to EAE", <u>J. Immunol.</u> , 1979, 123, 2156-2160 (Abstract)					
		Lando, et al., "Experimental Allergic Encephalomyelitis in Mice - Suppression and Prevention with COP-1", <u>Israel J. Med. Sci.</u> , 1979, 15, 868-869 (Abstract)					
		Lee, et al., "Peptide and Protein Drug Delivery" in <u>Advances in Parenteral Sciences</u> (Vincent H.L. Lee, ed., Marcel Dekker, Inc., 1990) 691-695					
		Li et al., "Glatiramer acetate blocks the activation of THP-1 cells by interferon- γ ", <u>Eur. J. Pharmacol.</u> , 1998, 342: 303-310					
		Lisak, et al., "Effect of Treatment with Copolymer I (Cop-1) on the in Vivo and in Vitro Manifestations of Experimental Allergic Encephalomyelitis (EAE)", <u>J. Neurol. Sci.</u> , 1983, 62, 281-293					
		Matsunaga et al., "Complementation of Class II A alleles in the immune response to (Glu-Lys-Tyr) polymers", <u>Yokohama Med. Bull.</u> , 1988, 39(1-2): 9-19 (Abstract)					
		Maurer et al., "Interpretations of immune responses of mice to poly(Glu60Lys40), its modified derivatives, and the terpolymers poly (Glu55Lys37Leu8) and poly (Glu56Lys37Ser7)", <u>Clin. Immunol. Immunopathol.</u> , 1980, 15(3): 344-356 (Abstract)					
✓		McDermott, et al., "Antigen-induced Suppression of Experimental Allergic Neuritis in the Guinea Pig", <u>J. Neurol. Sci.</u> , 1980, 46, 137-143					
EXAMINER D. N. 24		DATE CONSIDERED 12/14/04					
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office			Atty. Docket No. 60807-AA-PCT-US/ JPW/ GJG/DJK		Serial No. Not Yet Known <u>10792,311</u>	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)					Applicants: Alexander Gad and Dora Lis			
					Filing Date Herewith		Group Art Unit <u>1644</u>	
U.S. PATENT DOCUMENTS								
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
PNA		Pender, et al., Internal Med. Journal, 2002, 32: 554-563						
1		Porter, "Coating of Pharmaceutical Dosage Forms," in <u>The Science and Practice of Pharmacy</u> , Remington, 1995, 2, 1650-1659						
		Prat et al., "Lymphocyte Migration and Multiple Sclerosis: Relation with Disease Course and Therapy," <u>Ann. Neurol.</u> , 1999, 46: 253-256						
		Puri et al., "Modulation of the Immune Response in Multiple Sclerosis", <u>J. Immunol.</u> , 1997, 158, 2471-2476						
		Racke, et al., "Copolymer-1-induced Inhibition of Antigen-specific T Cell Activation: Interference with Antigen Presentation", <u>J. Neuroimmunol.</u> , 1992, 37, 75-84						
		Reilly, Jr., W.J., "Pharmaceutical Necessities" in <u>The Science and Practice of Pharmacy</u> , Remington 1995, 2, 1380-1416						
		Rolak, "Copolymer-I Therapy for Multiple Sclerosis", <u>Clin. Neuropharmacology</u> , 1987, 10(5), 389-396						
		Rothbard, et al., "Interactions Between Immunogenic Peptides and MHC Proteins", <u>Ann. Rev. Immunol.</u> , 1991, 9, 527-565						
		Salveti, et al., "Myelin Basic Protein T Cell Epitopes in Patients with Multiple Sclerosis", <u>Department of Neurological Sciences, University of Rome, La Sapienza</u> 1991, 72 (Abstract)						
		Schlegel, et al., "Prevention of Graft-Versus-Host Disease by Peptides Binding to Class II Major Histocompatibility Complex Molecules", <u>Blood</u> , 1994, 84(8), 2802-2810						
		Schlegel, et al., "Inhibition of Allorecognition and Prevention of Graft-vs-host Disease (GVHD) by GLAT, a Synthetic Polymer with Promiscuous Binding to Murine and Human MHC Class II Molecules", in <u>Am. Soc. Hematology, 37th Annual Meeting</u> , Seattle, WA (USA), December 1-5, 1995, 224a (Abstract)						
✓		Schwartz et al., "Gene complementation in the T lymphocyte proliferative response to poly (Glu57Lys38Tyr5): Evidence for effects of polymer handling and gene dosage", <u>J. Immunol.</u> , 1979, 123(1): 272-278 (Abstract)						
EXAMINER <u>ply n. 2/2</u>		DATE CONSIDERED <u>12/14/04</u>						
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 60807-AA-PCT-US/ JPW/ GJG/DJK		Serial No. Not Yet Known 16/792,311	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Alexander Gad and Dora Lis			
				Filing Date Herewith		Group Art Unit 1644	
U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
P.H.		Sela, et al., "Experimental Allergic Encephalomyelitis" in <u>Menarini Series on Immunopathology</u> , vol. 1, First Symposium of Organ Specific Autoimmunity, Cremona, Italy, June, 1977, (Miescher P.A. ed., Schwabe Co., Basel, 1978), 9-21					
		Sela, et al., "Suppressive Activity of COP-1 in EAE and its Relevance to Multiple Sclerosis", <u>Bull. Inst. Pasteur</u> , 1990, 88, 303-314					
		Sela, "Polymeric Drugs as Immunomodulatory Vaccines Against Multiple Sclerosis", <u>Makromol. Chem. Macromol. Symp.</u> , 1993, 70/71, 147-155					
		Starzl, <u>Transplantation Proceedings</u> , 1990, 22 (1, Suppl. 1), 5					
		Stark, "Expanded Clinical Trials of Treatments for Multiple Sclerosis (MS): Copolymer 1 (COP-1) Treatment Investigational New Drug (IND) Program", <u>Ann. Neurol.</u> , 1994, 36, 114-115					
		Sykes, "Immunobiology of Transplantation", <u>Faseb J.</u> , 1996, 10, 721-730					
		Tarcic et al., "Copolymer 1 (Copaxone) from an Idea to a Drug for Treatment of Multiple Sclerosis" Database HCAPLUS on STN, Israel: AN 1997:333270. Kim, Handasa Kim, 1997, 281(14), 16-18 (Abstract)					
		Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide", <u>Eur. J. Immunol.</u> , 1971, 1, 242-248					
		Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide", <u>Israel J. Med. Sci.</u> , 1971, 7, 630-631 (Abstract)					
		Teitelbaum, et al., "Protection Against Experimental Allergic Encephalomyelitis", <u>Nature</u> , 1972, 240, 564-566					
		Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis with Basic Polymers", <u>Eur. J. Immunol.</u> , 1973, 3, 273-279					
✓		Teitelbaum, et al., "Dose-response Studies on Experimental Allergic Encephalomyelitis Suppression by COP-1", <u>Israel J. Med. Sci.</u> , 1974, 10(9), 1172-1173					
EXAMINER		DATE CONSIDERED					
[Signature]		12/14/04					
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office			Atty. Docket No. 60807-AA-PCT-US/ JPW/ GJG/DJK		Serial No. Not Yet Known 18/792,311	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)					Applicants: Alexander Gad and Dora Lis		Filing Date Herewith	
							Group Art Unit 1644	
U.S. PATENT DOCUMENTS								
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
PJA		Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", <u>Clin. Immunol. Immunopath.</u> , 1974, 3, 256-262						
		Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis in Baboons by Cop 1", <u>Israel J. Med. Sci.</u> , 1977, 13, 1038 (Abstract)						
		Teitelbaum, et al., "Blocking of Sensitization to Encephalitogenic Basic Protein in Vitro by Synthetic Basic Copolymer (COP 1)" in <u>Cell Biology and Immunology of Leukocyte Function</u> (Academic Press, New York, 1979) 681-685						
		Teitelbaum, "Suppression of Experimental Allergic Encephalomyelitis with a Synthetic Copolymer - Relevance to Multiple Sclerosis", in <u>Humoral Immunity in Neurological Diseases</u> (Karcher D., Lowenthal A. & Strosberg A.D., eds., Plenum Publishing Corp., 1979) 609-613						
		Teitelbaum, et al., "Monoclonal Antibodies to Myelin Basic Protein Cross React with Synthetic EAE-suppressive Copolymer, COP 1" in <u>Proc. 7th Eur. Immunol. Mtg.</u> , Jerusalem, September 8-13, 1985 (Abstract)						
		Teitelbaum, et al., "Specific Inhibition of the T-cell Response to Myelin Basic Protein by the Synthetic Copolymer Cop 1", <u>Proc. Natl. Acad. Sci. USA</u> , 1988, 85, 9724-9728						
		Teitelbaum, et al., "Clinical Trial of Copolymer 1 in Multiple Sclerosis" <u>J. Israel Med. Assoc.</u> , 1989, CXVI(9), 453-456						
		Teitelbaum, et al., "Cross-reactions and Specificities of Monoclonal Antibodies Against Myelin Basic Protein and Against the Synthetic Copolymer 1", <u>Proc. Natl. Acad. Sci. (USA)</u> , 1991, 88, 9528-9532						
		Teitelbaum, et al., "Synthetic Copolymer 1 Inhibits Human T-cell Lines Specific for Myelin Basic Protein", <u>Proc. Natl. Acad. Sci. (USA)</u> , 1992, 89, 137-141						
		Teitelbaum, et al., "Immunological Parameters in a Multicenter Clinical Trial of COP1 in Multiple Sclerosis (MS): A 2-year Follow-up", <u>Neurol.</u> , 1994, 44(Suppl. 2), A358						
		Teitelbaum, et al., "Copolymer 1 Inhibits Chronic Relapsing Experimental Allergic Encephalomyelitis Induced by Proteolipid Protein (PLP) Peptides in Mice and Interferes with PLP-specific T Cell Responses", <u>J. Neuroimmunol.</u> , 1996, 64, 209-217						
		Teitelbaum, et al., "Copolymer 1 from the Laboratory to FDA", <u>Israel J. Med. Sci.</u> , 1997, 33, 280-284						
EXAMINER		DATE CONSIDERED						
PJA		12/14/04						
<p>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>								

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office			Atty. Docket No. 60807-AA-PCT-US/ JPW/GJG/DJK		Serial No. Not Yet Known <i>1,079,311</i>	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)					Applicants: Alexander Gad and Dora Lis			
					Filing Date Herewith		Group Art Unit <i>1644</i>	
U.S. PATENT DOCUMENTS								
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
<i>Polk</i>		Thompson, "MCQ Tutor: Medical Immunology Multiple Choice Questions", <u>Immunol. Today</u> , 1985, 6(4), 141						
		Tisch et al., "Antigen-specific immunotherapy: Is it a Real Possibility to Combat T-Cell-Mediated autoimmunity?" <u>Proc. Natl. Acad. Sci. U.S.A.</u> , 1994, 91, 437-438						
		Tranoy et al., "Epitope-specific regulation of the T cell repertoire: carrier recognition in association with I-E or I-A does not influence the restriction of hapten-specific T cells", <u>Eur. J. Immunol.</u> , 1985, 15(12): 1215-1221 (Abstract)						
		Van den Bogaerde, et al., "Induction of Long-Term Survival of Hamster Heart Xenografts in Rats", <u>Transplantation</u> , 1991, 52, 15-20						
		Van Noort, et al., International Review of Cytology, 1996, 178: 127-205						
		Webb, et al., "Further Studies on the Suppression of Experimental Allergic Encephalomyelitis by Synthetic Copolymer", <u>Israel J. Med. Sci.</u> , 1972, 8, 656-657						
		Wender, "Copolymer I (COP-I) in the Treatment of Multiple Sclerosis (letter)" <u>Neur. Neurochir. Pol.</u> , 1990, 24, 113						
		Weinshenker, et al., "Natural History and Treatment of Multiple Sclerosis", <u>Current Opinion in Neurol. and Neurosurgery</u> , 1992, 5, 203-211						
		Webb, et al., "In Vivo and in Vitro Immunological Cross-reactions between Basic Encephalitogen and Synthetic Basic Polypeptides Capable of Suppressing Experimental Allergic Encephalomyelitis", <u>Eur. J. Immunol.</u> , 1973, 3, 279-286						
		Webb, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", <u>Isr. J. Med. Sci.</u> , 1975, 11, 1388 (Abstract)						
		Webb, et al., "Molecular Requirements Involved in Suppression of EAE by Synthetic Basic Copolymers of Amino Acids", <u>Immunochem.</u> , 1976, 13, 333-337						
✓		Webster's II New Riverside University Dictionary, definition of "preventing", The Riverside Publishing Co., 1984, page 933						
EXAMINER		DATE CONSIDERED						
<i>J. A. S.</i>		<i>7/2/14/04</i>						
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

PTO 1449

10/792,311

filed 3/2/04 173

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 28

August 21, 2002, October 18, 2002, and June 25, 2003. The below listed references 162, 202 and 209 were cited by the Examiner on PTO Form 892 issued on March 25, 2003 in connection with U.S. Serial No. 09/816,989.

Accordingly, under 37 C.F.R. §1.98(d) copies of references 1-23, 25-27, and 30-209 are not required to be provided to the United States Patent and Trademark Office because they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

Copies of the below listed references 24, 28 and 29 are enclosed herewith as **Exhibits 1-3**.

1. U.S. Patent No. 3,849,550, issued November 19, 1974 (Teitelbaum, et al.);
2. U.S. Patent No. 3,991,210, issued November 9, 1976 (Shea);
3. U.S. Patent No. 4,339,431, issued July 13, 1982 (Gaffar);
4. U.S. Patent No. 5,204,099, issued April 20, 1993 (Barbier, et al.);
5. U.S. Patent No. 5,554,372, issued September 10, 1996 (Hunter et al.);

[Signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 29

6. U.S. Patent No. 5,583,031, issued December 10, 1996
(Stern);
7. U.S. Patent No. 5,591,629, issued January 7, 1997
(Rodriguez et al);
8. U.S. Patent No. 5,623,052, issued April 22, 1997
(McLean et al.);
9. U.S. Patent No. 5,627,206, issued May 6, 1997 (Hupe, et
al.);
10. U.S. Patent No. 5,668,117, issued September 16, 1997
(Shapiro et al.);
11. U.S. Patent No. 5,719,296, issued February 17, 1998
(Acton, III, et al.);
12. U.S. Patent No. 5,734,023, issued March 31, 1998
(Bishwajit et al.);
13. U.S. Patent No. 5,800,808, issued September 1, 1998
(Konfino, et al.);
14. U.S. Patent No. 5,858,964, issued January 12, 1999
(Aharoni, et al.);
15. U.S. Patent No. 5,886,156, issued March 23, 1999
(McLean et al.);
16. U.S. Patent No. 5,958,972, issued September 28, 1999
(Hupe, et al.);

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 30

17. U.S. Patent No. 5,981,589, issued November 9, 1999
(Konfino, et al.);
18. U.S. Patent No. 6,048,898, issued April 11, 2000
(Konfino, et al.);
19. U.S. Patent No. 6,054,430, issued April 25, 2000
(Konfino, et al.);
20. U.S. Patent No. 6,214,791 issued April 10, 2001
(Arnon, et al.);
21. U.S. Patent No. 6,342,476, issued January 29, 2002
(Konfino, et al.);
22. U.S. Patent No. 6,362,161, issued March 26, 2002,
(Konfino et al.);
23. U.S. Patent No. 6,514,938, issued February 4, 2003 (Gad
et al.);
24. U.S. Patent No. 6,620,847, issued September 16, 2003
(Konfino, et al.) (**Exhibit 1**)
25. U.S. Patent Publication No. US-2001-0055568-A1,
published December 27, 2001 (Gilbert et al.);
26. U.S. Patent Publication No. US-2002-0037848-A1,
published March 28, 2002 (Eisenbach-Schwartz et al.);

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
 Serial No. : Not Yet Known (Continuation of U.S. Serial
 No. 09/816,989, filed March 32, 2001)
 Filed : Herewith
 Page 31

27. U.S. Patent Publication No. US-2002-0107388-A1,
 published August 8, 2002 (Vandenbark);
28. U.S. Patent Publication No. 2002-0115103-A1 (U.S. Serial
 No. 09/816,989, filed March 23, 2001) published August
 22, 2002 (Gad et al.) (Exhibit 2). Applicants point out
 that 2002-0115103-A1 is a counterpart of PCT/US99/22402
 and U.S. Patent No. 6,514,938 (Items 49 and 23
 respectively) as well as the parent of the subject
 application;
29. Pending claims as of March 1, 2004 of U.S. Serial No.
 09/816,989 (Gad et al.) (Item 28).. U.S. Patent
 Publication No. 2002-0115103 A1, for the Examiner's
 convenience, (Exhibit 3);
30. U.S. Patent Publication No. US-2003-0004099-A1,
 published January 2, 2003 (Eisenbach-Schwartz et al.);
31. U.S. Serial No. 09/359,099, filed July 22, 1999
 (Strominger et al.);
32. U.S. Serial No. 09/487,793, filed January 20, 2000;
33. U.S. Serial No. 09/620,216, filed July 20, 2000;
34. U.S. Serial No. 09/765,301. Applicants point out that
 this reference is a counterpart of PCT International
 Application No. PCT/US01/02118 (WO 01/93893) (Item 54);

Py N. J.

12/14/04

Applicants : Alexander Gad and Dora Lis
 Serial No. : Not Yet Known(Continuation of U.S. Serial
 No. 09/816,989, filed March 32, 2001)
 Filed : Herewith
 Page 32

35. U.S. Serial No. 09/765,644. Applicants point out that this reference is a counterpart of PCT International Application No. PCT/US01/02117 (WO 01/52878) (Item 52);
36. U.S. Serial No. 09/875,429, filed June 5, 2001 (Yong and Chabot);
37. U.S. Serial No. 09/885,227, filed June 20, 2001 (Rodriguez and Ure);
38. PCT International Application No. PCT/US88/02139 (WO 88/10120), published December 29, 1988 (Weiner et al.);
39. PCT International Application No. PCT/EP91/01420 (WO 92/02543), published February 20, 1992 (Gaeta et al.);
40. PCT International Application No. PCT/US93/06249 (WO 94/03484), published February 17, 1994 (McLean et al.). Applicants point out that this reference is a counterpart of U.S. Patent No. 5,623,052 (Item 8) and U.S. Patent No. 5,886,156 (Item 15);
41. PCT International Application No. PCT/US94/05632 (WO 94/26774), published November 24, 1994 (Alexander et al.);
42. PCT International Application No. PCT/US95/04121 (WO 95/26980), published October 12, 1995 (Hackett et al.);
43. PCT International Application No. PCT/US94/05697 (WO 95/31997), published November 30, 1995 (Reid et al.);

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 33

44. PCT International Application No. PCT/US95/06551 (WO 95/31990), published November 30, 1995 (Konfino et al.). Applicants point out that this reference is a counterpart of U.S. Patents Nos. 5,800,808 (Item 13) and 6,342,476 (Item 21);
45. PCT International Application No. PCT/EP95/02125 (WO 95/33475), published December 14, 1995 (Kott et al.);
46. PCT International Application No. PCT/US98/00375 (WO 98/30227), published July 16, 1998 (Arnon et al.). Applicants point out that this reference is a counterpart of US Patent No. 6,214,791 (Item 20);
47. PCT International Application No. PCT/US99/16617 (WO 00/05249) published February 3, 2000 (Strominger et al.). Applicants point out that this reference is a counterpart of U.S. Serial No. 09/359,099 (Item 31);
48. PCT International Application No. PCT/US99/16747 (WO 00/05250) published February 3, 2000 (Aharoni et al.);
49. PCT International Application No. PCT/US99/22402 (WO 00/18794) published April 6, 2000 (Gad, et al.). Applicants point out that this reference is a counterpart of U.S. Patent No. 6,514,938 (Item 23) and U.S. Patent Publication No. 20020115103 (Item 28);
50. PCT International Application No. PCT/US99/22836 (WO 00/20010) published April 13, 2000 (Flechter, et al.);

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 34

51. PCT International Application No. PCT/US99/27107 (WO 00/27417) published May 18, 2000 (Aharoni et al.);
52. PCT International Application No. PCT/US01/02117 (WO 01/52878), published July 26, 2001 (Eisenbach-Schwartz et al.);
53. PCT International Application No. PCT/US01/05198 (WO 01/60392) published August 23, 2001 (Gilbert et al.)
Applicants point out that this reference is a counterpart of U.S. Patent Publication No. US-2001-0055568-A1 (Item 25);
54. PCT International Application No. PCT/US01/02118 (WO 01/93893), published December 13, 2001 (Eisenbach-Schwartz et al.);
55. PCT International Application No. PCT/US01/18248 (WO 01/93828) published December 13, 2001 (Yong and Chabot). Applicants point out that this reference is a counterpart of U.S. Serial No. 09/875,429 (Item 36);
56. PCT International Application No. PCT/US01/19649 (WO 01/97846) published December 27, 2001 (Rodriguez and Ure). Applicants point out that this reference is a counterpart of U.S. Serial No. 09/885,227 (Item 37);
57. European Patent Application No. 0 383 620 A2, published August 22, 1990 (Cook);
58. European Patent No. 0 359 783 B1, published November 29, 1995 (Werner, et al.);

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 35.

59. Abramsky, et al., "Effect of a Synthetic Polypeptide (COP-1) on Patients with Multiple Sclerosis and with Acute Disseminated Encephalomyelitis", J. Neurol. Sci., 1977, 31, 433-438;
60. Aharoni, et al., "T Suppressor Hybridomas and Interleukin-2-Dependent Lines Induced by Copolymer 1 or by Spinal Cord Homogenate Down-Regulate Experimental Allergic Encephalomyelitis", Eur. J. Immunol., 1993, 23, 17-25;
61. Aharoni, et al., "Studies on the Mechanism and Specificity of the Effect of the Synthetic Random Copolymer GLAT on Graft-versus-Host Disease", Immunol. Letters, 1997, 58, 79-87;
62. Alvord, et al., "Myelin Basic Protein Treatment of Experimental Allergic Encephalomyelitis in Monkeys", Ann. Neurol., 1979, 6, 469-473;
63. Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Copolymer Immunological Cross Reactive with Basic Encephalitogen", Israel J. Med. Sci., 1972, 8, 1759-1760;
64. Arnon, et al., "Suppression of EAE in Baboons by a Synthetic Polymer of Amino Acids", Neurol., 1978, 28, 336 (Abstract);

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 36

65. Arnon, et al., "Desensitization of Experimental Allergic Encephalomyelitis with Synthetic Peptide Analogues" in The Suppression of Experimental Allergic Encephalomyelitis and Multiple Sclerosis (Academic Press, New York, 1980) 105-107;
66. Arnon, "A Synthetic Copolymer of Amino Acids in a Clinical Trial for MS Therapy" in Progress in Multiple Sclerosis Research (Bauer, Ritter, eds., Springer Verlag New York, 1980) 416-418;
67. Arnon, "Experimental Allergic Encephalomyelitis - Susceptibility and Suppression", Immunological Rev., 1981, 55, 5-30;
68. Arnon, et al., "Suppression of Demyelinating Diseases by Synthetic Copolymers", in A Multidisciplinary Approach to Myelin Disease (G. Serlupi Crescenzi, ed., Plenum Publishing Corp., 1988) 243-250;
69. Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by Cop-1 - Relevance to Multiple Sclerosis", Israel J. Med. Sci., 1989, 25, 686-689;
70. Arnon, et al., "Immunomodulation of Experimental Allergic Encephalomyelitis", Israel J. Med. Sci., 1993, 29, 175-181;
71. Arnon, et al., "On the Existence of Suppressor Cells", Int. Arch. Allergy Immunol., 1993, 100, 2-7;

Py N. J.

12/14/04

10.830

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 37

72. Arnon, et al., "Immunospecific Drug Design - Prospects for Treatment of Autoimmune Disease", Therapeutic Immunol., 1994, 1, 65-70;
73. Babu et al., "Reevaluation of response patterns of nonresponder mice to GLPhe polymers", Immunogen., 1983, 18(1): 97-100 (Abstract);
74. Babu et al., "Ir gene control of T and B Cell Responses to Determinants in (Glu Lys Ala) Terpolymer", J. Immunogenet., 1984, 11(3-4): 251-254;
75. Bansil, et al., "Multiple Sclerosis: Pathogenesis and Treatment", Seminars in Neurol., June 1994, 14(2), 146-153;
76. Baumhefner, et al., "Copolymer 1 as Therapy for Multiple Sclerosis: The Cons", Neurol., 1988, 38(Suppl. 2), 69-71;
77. Baxevanis et al., "Genetic Control of T-Cell Proliferative Responses to Poly (Glu⁴⁰Ala⁶⁰) and Poly (Glu⁵¹Lys³⁴Tyr¹⁵): Subregion-Specific Inhibition of the Responses with Monoclonal Ia Antibodies", Immunogenetics, 1980, 11: 617-628;
78. Ben-Nun, et al., "The Autoimmune Reactivity to Myelin Oligodendrocyte Glycoprotein (MOG) in Multiple Sclerosis is Potentially Pathogenic: Effect of Copolymer 1 on MOG-induced Disease", J. Neurol., 1996, 243(Suppl. 1), S14-S22;

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
 Serial No. : Not Yet Known (Continuation of U.S. Serial
 No. 09/816,989, filed March 32, 2001)
 Filed : Herewith
 Page 38

79. Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", Ann. Neurol., 1980, 8, 117 (Abstract);
80. Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", Trans. Am. Neurol. Assoc., 1980, 105, 348-350;
81. Bornstein, et al., "Multiple Sclerosis: Trial of a Synthetic Polypeptide", Ann. Neurol., 1982, 11, 317-319;
82. Brosnan, et al., "The Response of Normal Human Lymphocytes to Copolymer 1", J. Neuropath. Exp. Neurol., 1983, 42, 356 (Abstract);
83. Bornstein, et al., "Clinical Trials of Copolymer 1 in Multiple Sclerosis", Ann. N.Y. Acad. Sci. (USA), 1984, 366-372;
84. Bornstein, et al., "Clinical Trials of a Synthetic Polypeptide (Copolymer 1) for the Treatment of Multiple Sclerosis" in Gonsett et al., Immunological and Clinical Aspects of Multiple Sclerosis (MTP Press, The Hague, 1984) 144-150;
85. Bornstein, et al., "Multiple Sclerosis: Clinical Trials of a Synthetic Polypeptide, Copolymer 1", Neurol., 1985, 35 (Suppl. 1), 103 (Abstract);

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 39

86. Bornstein, "Cop 1 May be Beneficial for Patients with Exacerbating-remitting Form of Multiple Sclerosis", Adv. Ther. (USA), 1987, 4, 206 (Abstract);
87. Bornstein, et al., "A Pilot Trial of Cop 1 in Exacerbating-remitting Multiple Sclerosis", New Eng. J. Med., 1987, 317(7), 408-414;
88. Bornstein, et al., "Clinical Experience with COP-1 in Multiple Sclerosis", Neurol., 1988, 38(Suppl. 2), 66-69;
89. Bornstein, et al., "Pilot Trial of COP-1 in Chronic Progressive Multiple Sclerosis: Preliminary Report", from The International Multiple Sclerosis Conference: An Update on Multiple Sclerosis, Roma (Italy), September 15-17, 1988, in Elsevier Science Publisher, 1989, 225-232;
90. Bornstein, et al., "Clinical Trials of Cop 1 in Multiple Sclerosis" in Handbook of Multiple Sclerosis (S.D. Cook Marcel Rekker, ed., 1990) 469-480;
91. Bornstein, et al., "A Placebo-controlled, Double-blind, Randomized Two-center, Pilot Trial of Cop 1 in Chronic Progressive Multiple Sclerosis", Neurol., 1991, 41, 533-539;
92. Bornstein, et al., "Treatment of Multiple Sclerosis with Copolymer 1" in Treatment of Multiple Sclerosis: Trial Design, Results and Future Perspectives (Rudick

pg. 39

12/14/01

Applicants : Alexander Gad and Dora Lis
 Serial No. : Not Yet Known(Continuation of U.S. Serial
 No. 09/816,989, filed March 32, 2001)
 Filed : Herewith
 Page 40

R.A. & Goodkin D.E., eds., Springer Verlag, London,
 1992) 173-198;

93. Brosnan, et al., "Copolymer 1: Effect on Normal Human Lymphocytes", Ann. N.Y. Acad. Sci. (USA), 1984, 436, 498-499;
94. Brosnan, et al., "Immunogenic Potentials of Copolymer 1 in Normal Human Lymphocytes", Neurol., 1985, 35, 1754-1759;
95. Burns, et al., "Human Cellular Immune Response in Vitro to Copolymer 1 and Myelin Basic Protein (MBP)", Neurol., 1985, 35 (Suppl. 1), 170 (Abstract);
96. Burns, et al., "Human Cellular Immune Response to Copolymer 1 and Myelin Basic Protein", Neurol., 1986, 36, 92-94;
97. Burns, et al., "Failure of Copolymer 1 to Inhibit the Human T-cell Response to Myelin Basic Protein", Neurol., 1991, 41, 1317-1319;
98. Carter, et al., "Newer Drug Therapies for Multiple Sclerosis", Drug Therapy, 1990, 31-32, 37-39, 42-43;

[Handwritten signature]

12/14/04

14930

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 41

99. Cazzato et al., "Treatment of Multiple Sclerosis. The Present and the Future. Study Group on Diagnosis and Therapy of Multiple Sclerosis", Database Medline on STN, Instituto do Clinica Neurologica, Universit'a, Trieste, Italy: Medline AN: 2000060325, Recent Progressi in Medicina, October 1999, 90(10): 538-544 (Abstract);
100. Clinical Trial Protocol No. 9001, Teva Pharmaceutical Industries, Ltd., first patient enrolled October 23, 1991);
101. Clinical Trial Protocol No. 9002, Lemmon Co. and Teva Pharmaceutical Industries, Ltd., first patient enrolled June 17, 1993;
102. Cohen, "Fundamental Immunology", Systemic Autoimmunity, 4th Ed., 1999, 1083;
103. The COP-1 Multicenter Clinical and Research Group Study, "COP-1 Multicenter Trial in Relapsing Remitting Multiple Sclerosis: 3 Year Follow Up", Abstracts of Symposia and Free Communication, Barcelona (Spain), June 25-29, 1994, 241 (Suppl. 1), 6;
104. Cotton, "Options for Multiple Sclerosis Therapy", J.A.M.A. Medical News & Perspectives, 1994, 272(18), 1393;
105. Deeb et al., "Comparision of Freund's and Ribi adjuvants for inducing antibodies to the synthetic antigen (TG)-AL in rabbits", J. Immunol. Methods, 1992, 152(1): 105-113 (Abstract);
- 12/14/94
- Pg. 41

15930

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 42

106. De Kruffy et al., "Analysis of T Cell Responses to Poly-L (GluLys) at the Clonal Level. I. Presence of Responsive Clones in Nonresponder Mice", Eur. J. Immunol., 1987, 17 (8): 1115-1120 (Abstract);
107. Dorling, et al., "Prospects for Xenografting", Curr. Opinions Immunol., 1994, 6, 765-769;
108. Durelli, "Immunotherapeutics of Multiple Sclerosis", Instituto di Clinica delle Malattie del Sistema Nervoso Universita di Torino, 467-475;
109. Falo et al., "Analysis of antigen presentation by metabolically inactive accessory cells and their isolated membranes", Proc. Natl. Acad. Sci. USA, 1985, 82(19): 6647-6651 (Abstract);
110. Ferrara, et al., "Graft-Versus-Host Disease", New Eng. J. Med., 1991, 324, 667-674;
111. Francis, "The Current Therapy of Multiple Sclerosis", J. Clin. Pharmacy and Therapeutics, 1993, 18, 77-84;
112. Fridkis-Hareli, et al., "Copolymer 1 Displaces MBP, PLP and MOG, but Can Not be Displaced by these Antigens from the MHC Class II Binding Site", Department of Chemical Immunology, The Weizmann Institute of Science, 1994;
113. Fridkis-Hareli, et al., "Direct Binding of Myelin Basic Protein and Synthetic Copolymer 1 to Class II Major

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 43

Histocompatibility Complex Molecules on Living Antigen-Presenting Cells - Specificity and Promiscuity", Proc. Natl. Acad. Sci. USA, 1994, 91, 4872-4876;

114. Fridkis-Hareli, et al., "Specific and Promiscuous Binding of Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", Israeli Biochem. Soc., 1994, 21-22 (Abstract);
115. Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells" in Neurochem Mtg., August 14-19, 1994;
116. Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen-Presenting Cells", J. Neurochem., 1994, 63 (Suppl. I), 561;
117. Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein do not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", Department of Chemical Immunology, The Weizmann Institute of Science, Rehovot, Israel, 1994;
118. Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Undergo Processing Prior to the Binding to Class II Major Histocompatibility

Pg. 43

12/14/04

17730

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 44

Complex Molecules on Antigen Presenting Cells", Israeli Immunol. Soc., May 3-4, 1994 (Abstract);

119. Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen-Presenting Cells", Cell. Immunol., 1995, 163, 229-236;
120. Fridkis-Hareli, et al., "Promiscuous Binding of Synthetic Copolymer 1 to Purified HLA-DR Molecules", J. Immunol., 1998, 160, 4386-4397;
121. Fridkis-Hareli, et al., "Synthetic Amino Acid Copolymers that Bind to HLA-DR Proteins and Inhibit Type II Collagen-Reactive T Cell Clones", Proc. Natl. Acad. Sci., 1998, 95, 12528-12531;
122. Fridkis-Hareli et al., "Binding of random copolymers of three amino acids to class II MHC molecules", Intl. Immunol., 1999, 11(5): 635-641;
123. Fridkis-Hareli et al., "Synthetic Peptides that Inhibit Binding of the Collagen Type II 261-273 Epitope to Rheumatoid Arthritis-Associated HLA-DR1 and DR4 Molecules and Collagen-Specific T-cell Responses", Database HCAPLUS on STN, Department of Clinical Immunology, Aarhus University Hospital, Aarhus, Denmark, HCAPLUS AN: 2000:455053, Human Immunology, 2000, 61(7): 640-650 (Abstract);
124. Grgacic, et al., "Cell-mediated Immune Response to Copolymer 1 in Multiple Sclerosis Measured by the

[Handwritten signature]

12/14/04

18730

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 45

Macrophage Procoagulant Activity Assay", Int. Immunol.,
1990, 2(8), 713-718;

125. Gurevich, "Study of the MHC-competition Between BP and
Cop 1 Using Human Cytotoxic T-cell Clones" Israel J.
Med. Sci., 1993 (Abstract);

126. Harrison and Hafler, "Antigen-Specific Therapy for
Autoimmune Disease", Current Opin. Immunol., 2000,
12(6): 704-711;

127. Henry, Celia M., "Special Delivery", Chem. and Eng.
News, Sept. 18, 2000, 49-54;

128. Herzenberg et al., "Lack of immune response gene
control for induction of epitope-specific suppression
by TGAL antigen", Nature, 1982, 295: 329-331
(Abstract);

129. Jacobs, et al., "Advances in Specific Therapy for
Multiple Sclerosis", Neurol., 1994, 7, 250-254;

130. Johnson, "Clinical Studies in Copolymer 1 Therapy for
Exacerbating-relapsing Multiple Sclerosis", in Congress
for Advances in the Understanding and Treatment of
Multiple Sclerosis, Boston (USA), Oct. 28-29, 1992;

131. Johnson, "Experimental Therapy of Relapsing-Relapsing
Multiple Sclerosis with Copolymer-1", Ann. Neurol.,
1994, 36(Suppl.), 115-117;

poly. n. g.

12/14/04

19730

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 46

132. Johnson, Management of Relapsing/Remitting Multiple Sclerosis with Copolymer 1 (Copaxone)", Chemical Abstracts, 1996, 125, 291993b;

133. Ju et al., "Idiotypic analysis of antibodies against the terpolymer L-glutamic acid 60-L-alanine30-L-tyrosine10 (GAT). IV. Induction of CGAT idiotypic following immunization with various synthetic polymers containing glutamic acid and tyrosine", Eur. J. Immunol., 1979, 9(7): 553-560 (Abstract);

134. Kay, et al., "The Mechanism of Action of FK 506", Transplantation Proceedings, 1990, 22(1, Suppl. 1), 96-99;

135. Keith, et al., "The Effect of COP 1, a Synthetic Polypeptide, on Chronic Relapsing Experimental Allergic Encephalomyelitis in Guinea Pigs" J. Neurol. Sci., 1979, 42, 267-274;

136. Keleman, et al., "Graft-versus-Host Disease in Bone Marrow Transplantation: Experimental, Laboratory, and Clinical Contributions of the Last Few Years", Int. Arch. Allergy Immunol., 1993, 102, 309-320;

137. Kepsutlu et al., "Evaluation of Chitosan Used as an Excipient in Tablet Formulations", Database HCAPLUS on STN, Department of Pharmaceutical Technology, Gulhane Military Medical Academy, Ankara, 06018, Turkey, HCAPLUS AN: 1999: 590411, Acta. Pol. Pharm. 1999, 56(3): 27-235 (Abstract);

Handwritten signature

12/14/04

20830

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 47

138. Kott, et al., "COP-1 Increases Suppressor Cells Number in Multiple Sclerosis", Israel Neurological Assoc., December 19-20, 1994, Herzliya (Israel), 17;
139. Kropshofer et al., "Self-Peptides from Four HLA-DR Alleles Share Hydrophobic Anchor Residues Near the NH₂-Terminal Including Proline as a Stop Signal for Trimming", J. Immunol., 1993, 151: 4732-4742;
140. Lai et al., "Complementation of Class II A alleles in the immune response to (GluLysTyr) polymers", Exp. Clin. Immunogenet., 1986, 3(1): 38-48 (Abstract);
141. Lai et al., "Monoclonal T cell responses to two epitopes on a single immunogen controlled by two distinct genes", J. Immunol., 1986, 136(10): 3799-3804 (Abstract);
142. Lando, et al., "Effect of Cyclophosphamide on Suppressor Cell Activity in Mice Unresponsive to EAE", J. Immunol., 1979, 123, 2156-2160 (Abstract);
143. Lando, et al., "Experimental Allergic Encephalomyelitis in Mice - Suppression and Prevention with COP-1", Israel J. Med. Sci., 1979, 15, 868-869 (Abstract);
144. Lee, et al., "Peptide and Protein Drug Delivery" in Advances in Parenteral Sciences (Vincent H.L. Lee, ed., Marcel Dekker, Inc., 1990) 691-695;

[Handwritten signature]

12/14/04

21830

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 48

145. Li et al., "Glatiramer acetate blocks the activation of THP-1 cells by interferon- γ ", Eur. J. Pharmacol., 1998, 342: 303-310;
146. Lisak, et al., "Effect of Treatment with Copolymer 1 (Cop-1) on the in Vivo and in Vitro Manifestations of Experimental Allergic Encephalomyelitis (EAE)", J. Neurol. Sci., 1983, 62, 281-293;
147. Matsunaga et al., "Complementation of Class II A alleles in the immune response to (Glu-Lys-Tyr) polymers", Yokohama Med. Bull., 1988, 39(1-2): 9-19 (Abstract);
148. Maurer et al., "Interpretations of immune responses of mice to poly(Glu60Lys40), its modified derivatives, and the terpolymers poly(Glu55Lys37Leu8) and poly(Glu56Lys37Ser7)", Clin. Immunol. Immunopathol., 1980, 15(3): 344-356 (Abstract);
149. McDermott, et al., "Antigen-induced Suppression of Experimental Allergic Neuritis in the Guinea Pig", J. Neurol. Sci., 1980, 46, 137-143;
150. Meiner, "COP-1 Multicenter Clinical Trial in Exacerbating-remitting Multiple-Sclerosis: One Year Follow-up", J. Neurol., 1991(Suppl. 1) (Abstract);
151. Meiner, et al., "The Israeli COP-1 Multicenter Clinical Trial in Exacerbating-remitting Multiple Sclerosis - Two-year Follow-up", in 9th Congress of the European Committee for Treatment and Research in Multiple

pg 2.7

12/14/01

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 49

Sclerosis, Florence (Italy), October-November, 1993, 48
(Abstract);

152. Mengle-Gaw, "The Major Histocompatibility Complex
(MHC)", in Encycl. Molecular Bio. (Oxford Blackwell
Science Ltd, 1994) 602-606;

153. Milo, et al., "Inhibition of Myelin Basic Protein-
specific Human T-cell Lines by COP-1", Israel J. Med.
Sci., 1992, 28, 486 (Abstract);

154. Milo, et al., "Copolymer-1 (COP-1) Regulates Class II
MHC Expression and Cytokine Synthesis in the THP-1
Monocyte-Macrophage Cell Line" in The IBC Conference on
Multiple Sclerosis, San Diego (USA), December 10, 1993
(Abstract);

155. Milo, et al., "Additive Effects of COP-1 and IFN-Beta
on Immune Responses to Myelin Basic Protein", Neurol.,
1994, 44 (Suppl. 2), A212;

156. Milo, et al., "Additive Effect of Copolymer-1 and
Interferon- β on the Immune Response to Myelin Basic
Protein", Assaf Harofeh Medical Center, Sackler School
of Medicine, Tel-Aviv University of Maryland School of
Medicine, 1994, 22;

157. Milo, et al., "Copolymer-1 and Interferon- β Additively
Suppress the Immune Response to Myelin Basic Protein by
Inhibiting Antigen Presentation", J. Neuroimmunol.,
1994, 54, 183 (Abstract);

[Handwritten signature]

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 50

158. Milo, et al., "Additive Effects of Copolymer-1 and Interferon β -1b on the Immune Response to Myelin Basic Protein", J. Neuroimmunol., 1995, 61, 185-193;
159. Myers, et al., "The Peculiar Difficulties of Therapeutic Trials for Multiple Sclerosis", Neurologic Clinics, 1990, 8(1), 119-141;
160. Nightingale, et al., "Access to Investigational Drugs for Treatment Purposes", Am. Family Physician, 1994, 50(4), 845-847;
161. O'Connor, et al., "Powders" in The Science and Practice of Pharmacy, Remington, 1995, 2, 1598-1614;
162. Pender, et al., Internal Med. Journal, 2002, 32: 554-563;
163. Porter, "Coating of Pharmaceutical Dosage Forms," in The Science and Practice of Pharmacy, Remington, 1995, 2, 1650-1659;
164. Prat et al., "Lymphocyte Migration and Multiple Sclerosis: Relation with Disease Course and Therapy," Ann. Neurol., 1999, 46: 253-256;
165. Puri et al., "Modulation of the Immune Response in Multiple Sclerosis", J. Immunol., 1997, 158, 2471-2476;
166. Racke, et al., "Copolymer-1-induced Inhibition of Antigen-specific T Cell Activation: Interference with

Handwritten signature

12/14/04

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 51

Antigen Presentation", J. Neuroimmunol., 1992, 37, 75-84;

167. Reilly, Jr., W.J., "Pharmaceutical Necessities" in The Science and Practice of Pharmacy, Remington 1995, 2, 1380-1416;

168. Rolak, "Copolymer-I Therapy for Multiple Sclerosis", Clin. Neuropharmacology, 1987, 10(5), 388-396;

169. Rothbard, et al., "Interactions Between Immunogenic Peptides and MHC Proteins", Ann. Rev. Immunol., 1991, 9, 527-565;

170. Salvetti, et al., "Myelin Basic Protein T Cell Epitopes in Patients with Multiple Sclerosis", Department of Neurological Sciences, University of Rome, La Sapienza 1991, 72 (Abstract);

171. Schlegel, et al., "Prevention of Graft-Versus-Host Disease by Peptides Binding to Class II Major Histocompatibility Complex Molecules", Blood, 1994, 84(8), 2802-2810;

172. Schlegel, et al., "Inhibition of Allorecognition and Prevention of Graft-vs-host Disease (GVHD) by GLAT, a Synthetic Polymer with Promiscuous Binding to Murine and Human MHC Class II Molecules", in Am. Soc. Hematology, 37th Annual Meeting, Seattle, WA (USA), December 1-5, 1995, 224a (Abstract);

Phy. S. J.

12/14/04

25830

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 52

173. Schwartz et al., "Gene complementation in the T lymphocyte proliferative response to poly (Glu57Lys38Tyr5): Evidence for effects of polymer handling and gene dosage", J. Immunol., 1979, 123(1): 272-278 (Abstract);
174. Sela, et al., "Experimental Allergic Encephalomyelitis" in Menarini Series on Immunopathology, vol. 1, First Symposium of Organ Specific Autoimmunity", Cremona, Italy, June, 1977, (Miescher P.A. ed., Schwabe Co., Basel, 1978), 9-21;
175. Sela, et al., "Suppressive Activity of COP-1 in EAE and its Relevance to Multiple Sclerosis", Bull. Inst. Pasteur, 1990, 88, 303-311;
176. Sela, "Polymeric Drugs as Immunomodulatory Vaccines Against Multiple Sclerosis", Makromol. Chem. Macromol. Symp., 1993, 70/71, 147-155;
177. Starzl, Transplantation Proceedings, 1990, 22 (1, Suppl. 1), 5;
178. Stark, "Expanded Clinical Trials of Treatments for Multiple Sclerosis (MS): Copolymer 1 (COP-1) Treatment Investigational New Drug (IND) Program", Ann. Neurol., 1994, 36, 114-115;
179. Sykes, "Immunobiology of Transplantation", Faseb J., 1996, 10, 721-730;
- 12/14/04

26930

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known(Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 53

180. Tarcic et al., "Copolymer 1 (Copaxone) from an Idea to a Drug for Treatment of Multiple Sclerosis" Database HCAPLUS on STN, Israel: AN 1997:333270. Kim, Handasa Kim, 1997, 281(14), 16-18 (Abstract);
181. Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide", Eur. J. Immunol., 1971, 1, 242-248;
182. Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide", Israel J. Med. Sci., 1971, 7, 630-631 (Abstract);
183. Teitelbaum, et al., "Protection Against Experimental Allergic Encephalomyelitis", Nature, 1972, 240, 564-566;
184. Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis with Basic Polymers", Eur. J. Immunol., 1973, 3, 273-279;
185. Teitelbaum, et al., "Dose-response Studies on Experimental Allergic Encephalomyelitis Suppression by COP-1", Israel J. Med. Sci., 1974, 10(9), 1172-1173;
186. Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", Clin. Immunol. Immunopath., 1974, 3, 256-262;

[Handwritten signature]

12/14/74

27830

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 54

187. Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis in Baboons by Cop 1", Israel J. Med. Sci., 1977, 13, 1038 (Abstract);
188. Teitelbaum, et al., "Blocking of Sensitization to Encephalitogenic Basic Protein in Vitro by Synthetic Basic Copolymer (COP 1)" in Cell Biology and Immunology of Leukocyte Function (Academic Press, New York, 1979) 681-685;
189. Teitelbaum, "Suppression of Experimental Allergic Encephalomyelitis with a Synthetic Copolymer - Relevance to Multiple Sclerosis", in Humoral Immunity in Neurological Diseases (Karcher D., Lowenthal A. & Strosberg A.D., eds., Plenum Publishing Corp., 1979) 609-613;
190. Teitelbaum, et al., "Monoclonal Antibodies to Myelin Basic Protein Cross React with Synthetic EAE-suppressive Copolymer, COP 1" in Proc. 7th Eur. Immunol. Mtg., Jerusalem, September 8-13, 1985 (Abstract);
191. Teitelbaum, et al., "Specific Inhibition of the T-cell Response to Myelin Basic Protein by the Synthetic Copolymer Cop 1", Proc. Natl. Acad. Sci. USA, 1988, 85, 9724-9728;
192. Teitelbaum, et al., "Clinical Trial of Copolymer 1 in Multiple Sclerosis" J. Israel Med. Assoc., 1989, CXVI(9), 453-456;

[Handwritten signature]

12/14/81

78230

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 55

193. Teitelbaum, et al., "Cross-reactions and Specificities of Monoclonal Antibodies Against Myelin Basic Protein and Against the Synthetic Copolymer 1", Proc. Natl. Acad. Sci. (USA), 1991, 88, 9528-9532;
194. Teitelbaum, et al., "Synthetic Copolymer 1 Inhibits Human T-cell Lines Specific for Myelin Basic Protein", Proc. Natl. Acad. Sci. (USA), 1992, 89, 137-141;
195. Teitelbaum, et al., "Immunological Parameters in a Multicenter Clinical Trial of COP1 in Multiple Sclerosis (MS): A 2-year Follow-up", Neurol., 1994, 44 (Suppl. 2), A358;
196. Teitelbaum, et al., "Copolymer 1 Inhibits Chronic Relapsing Experimental Allergic Encephalomyelitis Induced by Proteolipid Protein (PLP) Peptides in Mice and Interferes with PLP-specific T Cell Responses", J. Neuroimmunol., 1996, 64, 209-217;
197. Teitelbaum, et al., "Copolymer 1 from the Laboratory to FDA", Israel J. Med. Sci., 1997, 33, 280-284;
198. Thompson, "MCQ Tutor: Medical Immunology Multiple Choice Questions", Immunol. Today, 1985, 6(4), 141;
199. Tisch et al., "Antigen-specific immunotherapy: Is it a Real Possibility to Combat T-Cell-Mediated autoimmunity?" Proc. Natl. Acad. Sci. U.S.A., 1994, 91, 437-438;

[Handwritten signature]

12/14/01

29730

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001).
Filed : Herewith
Page 56

200. Trannoy et al., "Epitope-specific regulation of the T cell repertoire: carrier recognition in association with I-E or I-A does not influence the restriction of hapten-specific T cells", Eur. J. Immunol. 1985, 15(12): 1215-1221 (Abstract);
201. Van den Bogaerde, et al., "Induction of Long-Term Survival of Hamster Heart Xenografts in Rats", Transplantation, 1991, 52, 15-20;
202. Van Noort, et al., International Review of Cytology, 1996, 178: 127-205;
203. Webb, et al., "Further Studies on the Suppression of Experimental Allergic Encephalomyelitis by Synthetic Copolymer", Israel J. Med. Sci., 1972, 8, 656-657;
204. Wender, "Copolymer 1 (COP-1) in the Treatment of Multiple Sclerosis (letter)" Neur. Neurochir. Pol., 1990, 24, 113;
205. Weinshenker, et al., "Natural History and Treatment of Multiple Sclerosis", Current Opinion in Neurol. and Neurosurgery, 1992, 5, 203-211;
206. Webb, et al., "In Vivo and in Vitro Immunological Cross-reactions between Basic Encephalitogen and Synthetic Basic Polypeptides Capable of Suppressing Experimental Allergic Encephalomyelitis", Eur. J. Immunol., 1973, 3, 279-286;

[Handwritten signature]

12/26/04

30 of 30

Applicants : Alexander Gad and Dora Lis
Serial No. : Not Yet Known (Continuation of U.S. Serial
No. 09/816,989, filed March 32, 2001)
Filed : Herewith
Page 57

207. Webb, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", Isr. J. Med. Sci., 1975, 11, 1388 (Abstract);
208. Webb, et al., "Molecular Requirements Involved in Suppression of EAE by Synthetic Basic Copolymers of Amino Acids", Immunochem., 1976, 13, 333-337;
209. Webster's II New Riverside University Dictionary, definition of "preventing", The Riverside Publishing Co., 1984, page 933;
210. Winer, "COP 1 Therapy for Multiple Sclerosis", New Eng. J. Med., 1987, 317(7), 442-444;
211. Zisman et al., "Dichotomy between the T and the B cell epitopes of the synthetic polypeptide (T,G)-A--L", Eur. J. Immunol., 1994, 24(10): 2497-2505 (Abstract); and
212. Zisman et al., "Direct binding of a synthetic multichain polypeptide to Class II Major Histocompatibility Complex molecules on Antigen-Presenting Cells and stimulation of a specific T-cell line require processing of the polypeptide", Proc. Natl. Acad. Sci. USA, 1991, 88(21): 9732-9742 (Abstract).

Applicants request that the Examiner review the publications and make them of record in the subject application.

[Signature]

12/14/04